

REMARKS

The Final Office Action of October 20, 2004, has been received and reviewed. Claims 1-21 and 23-37 are pending in the application. Claims 1-21, 23, 25-35 and 37 stand rejected and claims 24 and 36 are objected to as being dependent on a rejected base claim. Applicant proposes to amend claims 1, 8, 9, 18, 27 and 35-37 as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is requested.

Rejections under 35 U.S.C. § 102

Claims 1-11, 13, 17-21, 23 and 25-35 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Roberts et al. Applicant respectfully traverses the rejections as set forth herein.

Amended claim 1 cannot be anticipated since Roberts et al. does not expressly or inherently disclose each and every element amended claim 1. As amended, claim 1 is directed to an electrotransport device for transporting molecules of a beneficial agent from a reservoir across a semipermeable membrane and into an ionic fluid comprising, *inter alia*, a first compartment including **an electropositive or an electronegative material** configured as a first electrode and a second electrode comprising **an electropositive or an electronegative material** in communication with the ionic fluid, wherein said electropositive or electronegative material of said first electrode is complementary to said electronegative or electropositive material of said second electrode, such that when electrically connected with the conductor and the ionic fluid, **a battery is formed.**

The Final Office Action asserted

Roberts et al. teaches an iontophoresis method and an apparatus for opthamalic delivery of a beneficial agent comprises two electrodes (10, 11), connected to a power source (12), and both configured to contain the beneficial agent that is to be delivered subcutaneously to the patient. The electrode has semi-permeable membrane (column 4, line 64) that contact with an ionic fluid of the patient. Contact of the membranes with the subject's tissue completes the circuit of the device.

(Final Office Action, page 2).

The Final Office Action also indicated that “an apparatus claim must have structural or element limitations that are different then the prior art in order to obtain a patent.” (*Id.* at page 4). Claim 1 includes elements directed towards electrodes having **electropositive or electronegative materials** and is novel since Roberts et al. does not disclose electrodes comprising an electropositive or an electronegative material. The as-filed specification indicates that the electropositive or the electronegative materials may “include the class of alkali metals, as well as various electropositive metals located on the right side of the periodic chart, such as Zn, Mg, and Al. In a preferred embodiment, the anode electrode comprises an electronegative metal such as Zn, Mg, Ca, Ba, Al, Sn, Fe, or combinations or alloys thereof.” (Specification, as-filed, paragraph [0040]). The specification also indicates that “Electronegative materials for use in the present invention include carbon, halides, chalcogenides and active metal oxides such as silver oxides, copper oxides, manganese dioxides, and mixtures and composites of any thereof.” (*Id.*) Roberts et al. does not disclose **any electropositive or electronegative materials** in the compartments of the iontophoresis apparatus. Rather, Roberts et al. indicates

[t]he type of electrodes utilized in the method of the invention may vary dependent upon the required application. If the donor electrode is to be applied topically, then such electrode will most commonly be in the form of a pad containing an active substance in solution having a backing metal plate or electrode. An example of such an electrode is the conventional gel type pad (such as IOMED). The donor electrode is usually placed on an outer body surface, such as skin, while the receptor electrode is an inserted electrode which may be a probe electrode suitably of the type hereinafter described or a needle electrode which is inserted directly into the tissue.

(Roberts et al., Col. 4, lines 17-28). Roberts et al. further states

[t]he needle electrode may also include an electrode body made of any suitable metal such as **platinum, silver or stainless steel**. A conductor or wire may pass through the electrode body and thus current may travel along the wire and continue along the needle. The wire may be connected to a source of electrical current.

(*Id.* at Col. 4, lines 39-44) (emphasis added). Thus, Roberts et al. does not expressly or inherently disclose the electropositive or electronegative materials of the compartments of the iontophoresis apparatus as recited in amended claim 1.

Further, as discussed in the Amendment filed July 19, 2004, since Roberts et al. discloses that “said first and second electrodes are each electrically connected to a power source [*i.e.*, a battery]” and Roberts et al. is silent with respect to the elements (*i.e.*, electropositive or electronegative materials) of the electrotransport device of claim 1 that do **form a battery**, the structure disclosed in Roberts et al. is not capable of performing the same function as the electrotransport device of amended claim 1. (*Id.* at Col. 3, lines 38-40). Thus, Roberts et al. does not disclose each and every element of amended claim 1 as required for anticipation.

Claims 2-11, 13 and 17 depend from amended claim 1 and, thus, include the elements of amended claim 1. Since Roberts et al. does not disclose each and every element of amended claim 1, Roberts et al. also cannot disclose each and every element of any of claims 2-11, 13 and 17 which include the elements of amended claim 1.

With further regard to claim 5, it cannot be anticipated since Roberts et al. does not expressly or inherently describe the first semipermeable membrane configured to conduct charged species from the first electrode when implanted under a subject’s skin surface **in whom the electrotransport device has been implanted** as recited in claim 5. In fact, Roberts et al. does not disclose any entire iontophoretic device that is implanted under a subject’s skin. (*See generally, Id.*).

Dependent claim 13 cannot be anticipated since Roberts et al. does not expressly or inherently describe an electrotransport device comprising a second semipermeable membrane disposed adjacently under at least a portion of the second compartment, the second semipermeable membrane configured to be in fluid communication with a second beneficial agent contained in the second compartment, the second semipermeable membrane adapted to be implanted under at least a portion of a subject’s stratum corneum in whom the **electrotransport device has been implanted**. Since Roberts et al. does not disclose any entire iontophoresis apparatus implanted under the skin of a subject, claim 13 cannot be anticipated.

With further regard to dependent claim 17, it cannot be anticipated since Roberts et al. does not disclose an electrotransport device having at least a portion of the first semipermeable membrane comprising **a material configured to be resorbable** by a subject’s body tissues in whom **the electrotransport device has been implanted**.

Amended independent claim 18 cannot be anticipated since Roberts et al. does not expressly or inherently disclose each and every element of amended claim 18. For instance, Roberts et al. does not disclose an electrotransport device for delivering molecules of a beneficial agent to tissue of a subject **upon implantation** comprising, *inter alia*, a plurality of mutually spaced apart electrodes, wherein at least one of said plurality of mutually spaced apart electrodes comprises **an electropositive or an electronegative material**, a semipermeable membrane disposed adjacently under the at least one reservoir, the semipermeable membrane adapted to be implanted under at least a portion of the tissue of a subject, wherein a subject's tissue completes a circuit between the plurality of mutually spaced apart electrodes upon implantation under the subject's skin surface and enables delivery of molecules of the beneficial agent to the subject as recited in amended independent claim 18.

As previously established herein, Roberts et al. does not disclose an electrode comprising an **electropositive or electronegative material**. Further, the entire iontophoresis apparatus of Roberts et al. is not configured for implantation as recited in amended independent claim 18. Rather, as stated in Roberts et al. "electrodes 27 and 28 may comprise a needle electrode, static probe, micro dialysis tubing or probe, conventional surface electrode, any surgically implanted electrode or conducting material introduced into the tissue on its surface or on the outside of the body." (*Id.* at Col. 6, lines 57-61). Thus, Roberts et al. discloses that an electrode (which is not electropositive or electronegative) may be placed into the tissue, not that the entire iontophoresis apparatus may be implanted. Since Roberts et al. fails to disclose each and every element of amended claim 18, it cannot be anticipated.

Claims 19-21, 23 and 25 depend from amended claim 18 and, thus, include the elements of amended claim 18. Since Roberts et al. does not disclose each and every element of amended claim 18, Roberts et al. also cannot disclose each and every element of any of claims 19-21, 23 and 25 which include the elements of amended claim 18.

Amended independent claim 27 cannot be anticipated since Roberts et al. does not expressly or inherently disclose a method of electrically facilitating the transport of a beneficial agent to a body tissue of a subject, the method comprising, *inter alia*, providing a plurality of electrodes configured to conduct electrical current in relation to said body tissue, wherein at least

one of said plurality of electrodes is **electropositive or electronegative**. As previously established herein, Roberts et al. does not disclose an electrode comprising an **electropositive or electronegative material**.

Further, Roberts et al. also does not disclose implanting at least a portion of the at least one semipermeable membrane beneath a subject's stratum corneum skin layer, wherein, **responsive to the implanting, a circuit is completed between the plurality of electrodes, thus transmitting a voltage** from the plurality of electrodes and the at least one semipermeable membrane to the body tissues as recited in amended claim 27. Roberts et al. does not disclose a voltage being transmitted in response to the act of implanting a semipermeable membrane, but rather is limited to the use of a **power source** to complete a circuit and deliver an active substance to tissue. (*See, Id.* at Col. 3, lines 36-40, Col. 6, lines 65-67 and claim 1). Thus, Roberts et al. cannot anticipate amended claim 27.

Claims 28-34 depend from amended claim 27 and, thus, include the elements of amended claim 27. Since Roberts et al. does not disclose each and every element of amended claim 27, Roberts et al. also cannot disclose each and every element of any of claims 28-34 which include the elements of amended claim 27.

With further regard to claim 31, it cannot be anticipated since Roberts et al. does not expressly or inherently describe **electrostatically repelling** the beneficial agent through the at least one semipermeable membrane.

Dependent claim 32 cannot be anticipated since Roberts et al. does not expressly or inherently describe **implanting the electrodes and the beneficial agent reservoir** under a skin surface of the subject. Roberts et al. is limited to inserting an electrode and, thus, does not identically disclose implanting a beneficial agent reservoir as recited in claim 32.

Dependent claim 34 cannot be anticipated since Roberts et al. does not expressly or inherently disclose **implanting a bottom-most surface** of the at least one impermeable membrane **to a depth approximating about 20-100 μ m** below the stratum corneum skin layer.

Amended independent claim 35 cannot be anticipated since Roberts et al. does not disclose an intraocular delivery device comprising a first electrode in fluid communication with the membrane and the beneficial agent, the first electrode comprising **an electropositive or an**

electronegative material; and a second electrode comprising **an electropositive or an electronegative material**, the second electrode configured to be in fluid communication with the subject's conjunctiva, but, except for conductive material connecting said first and second electrodes, electrically isolated from said first electrode, said first and second electrodes being selected, when configured together as a circuit, to **form a battery**.

As previously established herein, Roberts et al. does not disclose any electrode comprising **an electropositive or an electronegative material** that is in fluid communication with a beneficial agent or a subject's conjunctiva. Roberts et al. also does not disclose first and second electrodes being configured such that when configured together as a circuit, **a battery is formed** as recited in amended claim 35. As previously established herein, the elements (which are not electropositive or electronegative) of the iontophoresis apparatus of Roberts et al. are not capable of forming a battery since a separate power source is used. Thus, amended claim 35 cannot be anticipated.

Claim 37 depends from amended claim 35 and, thus, includes the elements of amended claim 35. Since Roberts et al. does not disclose each and every element of amended claim 35, Roberts et al. also cannot disclose each and every element of claim 37 which includes the elements of amended claim 35.

Reconsideration and withdrawal of the anticipation rejections of claims 1-11, 13, 17-21, 23 and 25-35 are requested.

Rejections under 35 U.S.C. § 103

Claim 12

Claim 12 stands rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Roberts et al. as applied to claims 1-11, 13, 17-21, 23 and 25-35, and further in view of Haak et al. Applicant respectfully traverses the rejection as hereinafter set forth.

Claim 12 depends from amended claim 1 and, thus, includes the elements of amended claim 1. Since Roberts et al. does not teach or suggest each and every element of base claim 1, Roberts et al. and Haak et al. cannot teach or suggest each and every element of claim 12 which includes the elements of amended claim 1 as required for obviousness.

Reconsideration and withdrawal of the obviousness rejection of claim 12 are requested.

Claims 14-16 and 37

Claims 14-16 and 37 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Roberts et al. as applied to claims 1-11, 13, 17-21, 23 and 25-35 and further in view of Theeuwes et al. Applicant respectfully traverses the rejection as set forth herein.

Claims 14-16 depend from amended claim 1 and claim 37 depends from amended claim 35. Thus, claims 14-16 include the elements of amended claim 1 and claim 37 includes the elements of amended claim 35. Since Roberts et al. does not teach or suggest each and every element of base claims 1 and 35, Roberts et al. and Theeuwes et al. also cannot disclose each and every element of claims 14-16 and 37 which include the elements of amended claims 1 and 35, respectively.

Reconsideration and withdrawal of the obviousness rejection of claims 14-16 and 37 are requested.

ENTRY OF AMENDMENTS

The proposed amendments to claims 1, 8, 9, 18, 27 and 35-37 should be entered by the Examiner because they are supported by the as-filed specification and do not add any new matter. For instance, the amendment to claim 1 merely clarifies that the electropositive or electronegative material is used to configure the first electrode and the second electrode. Further, the amendments do not raise new issues or require a further search since the element added to amended independent claims 1, 18, 27 and 35 (*i.e.*, an electrode comprising an electropositive or an electronegative material) was present in other pending claims (*see, e.g.*, claim 1) and should have already been searched. The amendments should also be entered since they should place the application in condition for allowance. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, the proposed amendments should be entered since they certainly remove issues for appeal.

CONCLUSION

In view of the proposed amendments and remarks set forth herein, applicant submits that the claims define patentable subject matter and a notice of allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly invited to contact the applicant's attorney at the address or telephone number herein.

Respectfully submitted,



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Date: February 15, 2005

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